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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,174	08/29/2001	Ish Kumar Khanna	SO3285-US	6799
28997	7590	04/20/2005	EXAMINER	
HARNESS, DICKEY, & PIERCE, P.L.C 7700 BONHOMME, STE 400 ST. LOUIS, MO 63105			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	
DATE MAILED: 04/20/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,174

Applicant(s)

KHANNA ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-11, 13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 10, 11, 13 and 15 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 8-11, 13 and 15 are pending in the application.

This action is in response to applicant's amendment filed December 13, 2004.

Claims 8-11, 13 and 15 have been amended.

Response to Amendment

The applicant's amendments filed December 13, 2004 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 10, 11, 13 and 15 maintained in the last office action labeled paragraph 1, the applicant's arguments have been fully considered, however they were not found persuasive. The applicant's stated that claims 11, 13 and 15 are directed to methods of using a compound, enantiomer, tautomer, racemate, polymorph, or salt of claim 8 to treat the various conditions recited in those claims. The applicants point to Reynolds at page 33 where "the efficacy of $\alpha_v\beta_3$ antagonists in angiogenesis inhibition is not in dispute here--- such inhibitors may yet prove to be effective thereapeutics" which is speculative to future uses of $\alpha_v\beta_3$ antagonists in angiogenesis inhibition. The applicants also state that Sheppard (October 1, 2002) called into question the dependability of Reynolds et al.'s reported findings and conclusions and Weng (May 27, 2003) hypothesize that Reynolds et al.'s, reported may have been influenced by increases expression of the vascular endothelial growth factor receptor Flk-1 which is proatherogenic in apoE-null mice. The applicants' claims must be enabled at the time of filing of which neither of the references provided by the applicants, were public knowledge prior to the applicants filing date.

Furthermore, Sheppard states that several integrins have been implicated in vascular development and angiogenesis, however, there is controversy about the principal integrins involved in this regulation in vivo as well as the mechanism by which these integrins regulate normal and pathological blood vessel development.

Evidence involving a single compound and two types of cancer was not found sufficient to establish the enablement of claims directed to a method of treating seven types of cancer with members of a class of several compounds. *In re Buting*, 163 USPQ 689. The remarkable advances in chemotherapy have seen the development of specific compounds to treat specific types of cancer. The great diversity of diseases falling within the “cancer” category means that it is contrary to medical understanding that any agent (let alone a genus of thousands of compounds) could be generally effective against such diseases. The intractability of these disorders is clear evidence that the skill level in this art is low relative to the difficulty of the task.

As stated in the MPEP, 2164.08 “[t]he Federal Circuit has repeatedly held that “the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation’.” *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a “reasonable correlation” to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). As concerns the

breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. In re Moore, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged "pioneer status" of invention irrelevant to enablement determination)."

Claims 10, 11, 13 and 15 are rejected under 35 U.S.C. 1 12, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. The applicants amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection labeled 2h) maintained in the last office action, which is hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled g), the applicant's amendments and remarks have been fully considered but they are not persuasive.

g) The applicants' stated that they have provided their reasoning in the above section supporting their belief that the enablement rejection of claims 10, 11, 13 and 15 should be withdrawn. The applicants also stated that there is no indication in this rejection (or the enablement rejection upon which this rejection is based) as to which terms in claims 10, 11, 13 and 15 are indefinite. However, the office action Mailed on February 11, 2004 emphasizes the terms, i.e. **tumor** metastasis, **tumor** growth, solid **tumor** growth, **neoplasia**, etc.

Claims 10, 11, 13 and 15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

3. The applicants amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection labeled 3b) in the last office action, which is hereby **withdrawn**.

4. With regards to the obviousness-type double patenting rejection of claims 8-16 of the last office action, the applicant's arguments have been fully considered, however they were not found persuasive. The applicants stated that no subject matter of either application has yet been found to be allowable and submit that this rejection is premature. However, as stated in the last office action this is a **provisional** (because the conflicting claims have not in fact been patented) obviousness-type double patenting rejection between two applications.

Claims 8-11, 13 and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-15 of copending Application No. 10/363,070, for reasons of record and stated above.

5. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejections labeled paragraph 5 in the last office action, which are hereby **withdrawn**.

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6. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 6 in the last office action, which are hereby **withdrawn**.

7. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 7 in the last office action, which is hereby **withdrawn**.

In view of the amendment dated December 13, 2004, the following new grounds of rejection and/or reinstated rejections apply.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 8, 10, 11, 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) The amendment to the definition of A¹, where the two moieties in line 4, page 9 of the amendment, i.e. 3-amino-isoquinolin-1-yl and 3-methylamino-isoquinolin-1-yl are not defined in the specification with respect to the genus.

- b) The amendment to the definition of A¹, where the two moieties in line 6, page 9 of the amendment, i.e. benzoxazol-2-ylamino and benzothiazol-2-ylamino are not defined in the specification with respect to the genus.
- c) The amendment to the definition of A¹, where the second moiety in line 4 on page 13 as well as the two moieties in lines 5 and 6, page 13, and the first moiety in line 1 on page 14 of the amendment, i.e. pyridyl-1,4-diazocin-5-one are not defined in the specification with respect to the genus.
- d) The amendment to the definition of A¹, where the first moiety in line 5 on page 15 as well as the two moieties in line 6, page 15 and all of the moieties on pages 156 and 17 of the amendment, i.e. quinolin-7-yl are not defined in the specification with respect to the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 8, 10, 11, 13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

- a) Claim 8 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of A¹ where the moiety in line 8 on page 10 has a nitrogen atom, which is not valence satisfied.

Claim Objections

10. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda L. Coleman
Primary Examiner Art Unit 1624
April 18, 2005